



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

|                                      |             |                      |                     |                  |
|--------------------------------------|-------------|----------------------|---------------------|------------------|
| APPLICATION NO.                      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/049,968                           | 02/13/2002  | Heinrich Wieland     | 38891.00100         | 6225             |
| 38647                                | 7590        | 03/04/2009           | EXAMINER            |                  |
| MILBANK, TWEEDE, HADLEY & MCCLOY LLP |             |                      | HANLEY, SUSAN MARIE |                  |
| INTERNATIONAL SQUARE BUILDING        |             |                      |                     |                  |
| 1850 K STREET, N.W., SUITE 1100      |             |                      |                     |                  |
| WASHINGTON, DC 20006                 |             |                      | ART UNIT            | PAPER NUMBER     |
|                                      |             |                      | 1651                |                  |
|                                      |             |                      | MAIL DATE           |                  |
|                                      |             |                      | 03/04/2009          |                  |
|                                      |             |                      | DELIVERY MODE       |                  |
|                                      |             |                      | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |
|------------------------------|--------------------------------------|---------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/049,968 | <b>Applicant(s)</b><br>WIELAND ET AL. |
|                              | <b>Examiner</b><br>SUSAN HANLEY      | <b>Art Unit</b><br>1651               |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 November 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 54-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 54-71 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/DP/0656)        | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

The amendment and remarks filed 11/13/08 are acknowledged.

Claims 54-71 are pending.

A new requirement for lack of unity is called for because Applicant has added new claim 71, drawn to a method for controlling hair growth in a subject in need thereof by the administration of an aromatase inhibitor. The originally restricted claims (27-52) did not recite hair as a collagen-containing specie. Furthermore, Applicant has reinstated subject matter that was previously cancelled (claim 70). Hence, the scope of the claimed subject matter is widened and a lack of unity is found for the following reasons:

***Election/Restrictions***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- I. A method for identifying and treating a subject suffering from a collagen deficient condition selected from the group consisting of wrinkles, strias, atony of the skin or sun exposure to the skin by the administration of an aromatase inhibitor;
- II. A method for identifying and treating a subject suffering from an injured tendon, ligament or other collagen containing part of the body by the administration of an aromatase inhibitor;

III. A method for influencing the rate of hair growth by identifying a subject in need thereof and administering an aromatase inhibitor.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 54-69 correspond to specie I.  
Claim 70 corresponds to specie II.  
Claim 71 corresponds to specie III.

New claim 70 is drawn to a method of treating injured ligaments, tendon or  
The following claim(s) are generic: No claim is generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: A "special technical feature" is defined by PCT Rule 13.2 as "those technical features that define a

contribution which each of the claimed inventions, considered as a whole, makes over the prior art." In the instant case, as discussed below, at least one of the claimed inventions fails to make any contribution over the prior art. When a claimed invention fails to make any contribution over the prior art, the claims as filed fail to contain a single common special technical feature supporting a showing unity of invention.

Specifically, Messenger et al. (US 6020327) disclose and claim a method for reducing the regression of hair growth comprising contacting a subject in need thereof with an aromatase inhibitor comprising 4-OH androstenedione (see claims 3 and 10). The disclosure of Messenger demonstrates that the control of hair growth and "any collagen containing part of the body (e.g. hair) was disclosed at the time of filing of the instant application. Hence, the species II and III fail to make a contribution over the prior art, it is clear that all claims as filed fail to provide special technical feature common to all claimed inventions. Because the claims as filed lack a common special technical feature, the claims lack unity.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 1651

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/  
Examiner, Art Unit 1651

/Michael G. Wityshyn/  
Supervisory Patent Examiner, Art Unit 1651